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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,880	04/19/2004	Joel M. Blatt	BAYER 3.0-003 CONT	9880
74144	7590	02/04/2009		
BAYER LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 South Avenue West Westfield, NJ 07090			EXAMINER NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	
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			02/04/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,880	<b>Applicant(s)</b> BLATT ET AL.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-60 and 68-76 is/are pending in the application.
- 4a) Of the above claim(s) 68-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The amendment dated 14 October 2008 has been received. Claims 1-50 and 61-67 have been canceled.
2. Claims 68-76 have been added.
3. Claims 51-60 and 68-76 are pending.

### ***Election/Restrictions***

4. Newly submitted claims 68-76 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 68-76 are directed to a device in which the labeled reagent binds to the analyte where as in the device of claims 51-60, the labeled reagents do not bind to the analyte.

Group I, claims 51-60, classified in 435, subclass 7.93, for example.

Group II, claims 68-76, classified in 435, subclass 7.94, for example.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 68-76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 51-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Guirguis (US 2002/0160538).

Fitzpatrick discloses a device and method comprising a pathway of three zones, a first mobilization zone (i.e. sample application zone), a second trap zone (i.e. test zone), and a third detection zone (i.e. reference zone), arranged so that the first and the third zone are spaced apart by the second zone. Labeled receptor specific for the analytes is provided on the first zone, the second zone has immobilized ligand (that binds to the labeled reagent when analyte is not present producing a signal that is inversely proportional to the concentration of analyte), the third zone provides for detection a receptor-analyte complex which positively correlates with the presence of analyte in the sample. See column 2, lines 26-36. Fitzpatrick teaches that any arrangement that provides a series of three or more zones in communication so that liquid will move from the first zone through the second into the third zone may be used. Column 3, lines 27-37. In addition to the basic three zones, the sample pathway may also include an application zone for applying sample, and an absorbent zone which facilitates movement of the sample through the zones as well as a control zone. See column 3, lines 37-49.

With respect to claims 52, 53 and 55, Fitzpatrick teaches that the solid support may be a sheet or film with the zones arrayed sequentially along a sample pathway. Other suitable solid phase supports includes nylon, coated plastic and glass, filters, paper, membranes, etc. See column 2, lines 51-68.

With respect to claim 54, Fitzpatrick discloses the possible detection of more than one analytes and appropriate modifications therein. See column 10, lines 47-51.

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With respect to claim 56, Fitzpatrick teaches the use of reagents such as antibodies, antigens, etc. See columns 5-7.

With respect to claim 57, Fitzpatrick discloses an application zone that functions as a filter for removing undesirable particles from a sample. See column 9, lines 30-32.

With respect to claim 58, Fitzpatrick teaches labels selected from colloidal gold, dye polymers, colored latex particles, or enzyme conjugated to receptors such as antibodies or antigens. See column 4, lines 26-34 and column 8, lines 30-37.

With respect to claim 59, Fitzpatrick teaches the first reagent in the trap zone is an immobilized ligand comprising an analog of the analyte. See column 7, line 3 through column 8, line 10.

With respect to claim 60, Fitzpatrick teaches that the second reagent is an immobilized binding partner (i.e. an antibody) that binds to the labeled receptor that is bound to the analyte. Detection of signal provides a positive correlation to the concentration of analyte. See column 8, line 13 through column 9, line 15.

Fitzpatrick is silent with respect to the detection of analyte concentration and Fitzpatrick does not specifically teach that the different zones of the test strip contains a pre-determined amount of reagents which is based upon the pre-determined range of analyte concentration.

Guirguis teaches a test strip where one or more reagents are immobilized in a corresponding number of reaction zones. Guirguis teaches that one skilled in the art will recognize that a desired amount of capture reagent can be immobilized in the reaction zone, and that a threshold concentration of bound reagent may be used to detect a predetermined amount of analyte. Guirguis teaches one embodiment where the detection device includes several reaction

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zones, each reaction zone for a different analyte, and each reaction zone includes a predetermined threshold concentration of bound reagent to detect a predetermined amount of analyte. Guirguis teaches that threshold concentration includes the lower limit of a concentration for an analyte. Guirguis also teaches a device including several reaction zones, each reaction zone including a different threshold concentration for the same analyte. In this embodiment, the threshold concentration provides a reference point for determining the upper limit of an analyte concentration range. See paragraph [0109].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize a predetermined amount of capture reagents in the different zones of the device of Fitzpatrick as taught by Guirguis because the process for using predetermined amount of assay reagents based upon a predetermined range of analyte is well known in the art as clearly taught by Guirguis.

Even though Fitzpatrick does not specifically state that the detectable response in the test zone plus the detectable response in the reference zone equal a total detectable response that is substantially constant for a pre-determined range of analyte concentration, Fitzpatrick anticipates the instant claims because this wherein clause is nothing more than an intended use of the device. In other words, it does not alter the structure of the device which is taught in its entirety by Fitzpatrick. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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***Response to Arguments***

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,039,607 Skold et al which discloses a device where if analyte is present in the sample, the analyte binds to the antibody immobilized to a first strip and the enzyme labeled analyte analog does not bind to this antibody and migrates to a second strip. The amount of the first analyte, therefore, must be a predetermined amount based on the suspected concentration range of the interest of the analyte.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
February 1, 2009